



## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021, please refer to the [EMA](#) website.

### Zactran 150 mg/ml Solution for Injection for Cattle, Sheep and Pigs Vm 04491/5061

• 12 June 2024	Addition of a manufacturer responsible for batch control arrangements and quality testing of the finished product. Addition of a manufacturer responsible for batch control arrangements and quality testing of the finished product. Addition of a manufacturer responsible for batch control arrangements and quality testing of the finished product. Addition of a manufacturer responsible for batch release including batch control or testing of the finished product. Addition of a secondary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
• 12 June 2024	Minor changes to an approved test procedure for an active substance. Minor changes to an approved test procedure for an active substance.
• 12 June 2024	Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an active substance.
• 19 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
• 26 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
• 26 April 2023	Deletion of a manufacturer of the active substance.
• 15 February 2022	Changes to the labelling and/or package leaflet.
• 19 January 2022	Change in the name/address of starting material used in the manufacture of the active substance.
• 25 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
• 01 March 2021	Change in the SPC, labelling or package leaflet due to new data.